TAB 17

(a) The purpose of conducting clinical investigations of a drug is to distinguish the effect of a drug from other influences, such as spontaneous change in the course of the disease, placebo effect, or biased observation. The characteristics described in paragraph (b) of this section have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation. The Food and Drug Administration considers these characteristics in determining whether an investigation is adequate and well-controlled for purposes of section 505 of the act. Reports of adequate and well-controlled investigations provide the primary basis for determining whether there is "substantial evidence" to support the claims of effectiveness for new drugs. Therefore, the study report should provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.

(b) An adequate and well-controlled study has the following characteristics:

(1) There is a clear statement of the objectives of the investigation and a summary of the proposed or actual methods of analysis in the protocol for the study and in the report of its results. In addition, the protocol should contain a description of the proposed methods of analysis, and the study report should contain a description of the methods of analysis ultimately used. If the protocol does not contain a description of the proposed methods of analysis, the study report should describe how the methods used were selected.

(2) The study uses a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect. The protocol for the study and report of results should describe the study design precisely; for example, duration of treatment periods, whether treatments are parallel, sequential, or crossover, and whether the sample size is predetermined or based upon some interim analysis. Generally, the following types of control are recognized:

(i) Placebo concurrent control. The test drug is compared with an inactive preparation designed to resemble the test drug as far as possible. A placebo-controlled study may include additional treatment groups, such as an active treatment control or a dose-comparison control, and usually includes randomization and blinding of patients or investigators, or both.

(ii) Dose-comparison concurrent control. At least two doses of the drug are compared. A dose-comparison study may include additional treatment groups, such as placebo control or active control. Dose-comparison trials usually include randomization and blinding of patients or investigators, or both.

(iii) No treatment concurrent control. Where objective measurements of effectiveness are available and placebo effect is negligible, the test drug is compared with no treatment. No treatment concurrent control trials usually include randomization.

(iv) Active treatment concurrent control. The test drug is compared with known effective therapy; for example, where the condition treated is such that administration of placebo or no treatment would be contrary to the interest of the patient. An active treatment study may include additional treatment groups, however, such as a placebo control or a dose-comparison control. Active treatment trials usually include randomization and blinding of patients or investigators, or both. If the intent of the trial is to show similarity of the test and control drugs, the report of the study should assess the ability of the study to have detected a difference between treatments. Similarity of test drug and active control can mean either that both drugs were effective or that neither was effective. The analysis of the study should explain why the drugs should be considered effective in the study, for example, by reference to results in previous placebo-controlled studies of the active control drug.

(v) Historical control. The results of treatment with the test drug are compared with experience historically derived from the adequately documented natural history of the disease or condition, or from the results of active treatment, in comparable patients or populations. Because historical control populations usually cannot be as well assessed with

respect to pertinent variables as can concurrent control populations, historical control designs are usually reserved for special circumstances. Examples include studies of diseases with high and predictable mortality (for example, certain malignancies) and studies in which the effect of the drug is self-evident (general anesthetics, drug metabolism).

(3) The method of selection of subjects provides adequate assurance that they have the disease or condition being studied, or evidence of susceptibility and exposure to the condition against which prophylaxis is directed.

(4) The method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables such as age, sex, severity of disease, duration of disease, and use of drugs or therapy other than the test drug. The protocol for the study and the report of its results should describe how subjects were assigned to groups. Ordinarily, in a concurrently controlled study, assignment is by randomization, with or without stratification.

(5) Adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data. The protocol and report of the study should describe the procedures used to accomplish this, such as blinding.

(6) The methods of assessment of subjects' response are well-defined and reliable. The protocol for the study and the report of results should explain the variables measured, the methods of observation, and criteria used to assess response.

(7) There is an analysis of the results of the study adequate to assess the effects of the drug. The report of the study should describe the results and the analytic methods used to evaluate them, including any appropriate statistical methods. The analysis should assess, among other things, the comparability of test and control groups with respect to pertinent variables; and the effects of any interim data analyses performed.

(c) The Director of the Center for Drug Evaluation and Research may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in paragraph (b) of this section with respect to a specific clinical investigation, either prior to the investigation or in the evaluation of a completed study. A petition for a waiver is required to set forth clearly and concisely the specific criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical investigation, what alternative procedures, if any, are to be, or have been employed, and what results have been obtained. The petition is also required to state why the clinical investigations so conducted will yield, or have yielded, substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(d) For an investigation to be considered adequate for approval of a new drug, it is required that the test drug be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(e) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

21 C. F. R. § 314.126

21 CFR § 314.126

END OF DOCUMENT

TAB 18

hearing will be transcribed as required in § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any disabled persons requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until December 29, 1995.

IV. Additional Request for Information

In order to assess the costs and benefits of enhanced OTC drug product labeling, written submissions to FDA on the following topics would be helpful:

(1) How frequently do companies reprint OTC drug product labels and labeling? How frequently are labels redesigned?

(2) What are the itemized costs involved in changing OTC drug labels and labeling (e.g., design, plate, reprinting, additional colors)?

(3) If FDA were to propose a new OTC drug labeling format, what strategies could be used to lessen the cost to industry? For example, what lead time would allow manufacturers to use up existing labeling inventories?

(4) What are the benefits to consumers from improvements in OTC drug labeling?

Written comments addressing cost components should address, where applicable, one-time versus annual costs, differences in brand versus private-label costs, and implications for small businesses. The agency is most interested in cost data expressed in dollars, staff hours, and personnel (professional, technical, or support). Quantitative measures of benefits are considered most desirable, but discussions of anecdotal and/or qualitative benefits are also welcomed. Submit comments to the Dockets Management Branch (address above) identified with Docket No. 95N–0259.

Dated: August 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–20245 Filed 8–15–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0227]

Direct-to-Consumer Promotion; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding direct-to-consumer promotion of prescription drugs. The purpose of the hearing is to solicit information from, and the views of, interested persons, including health care professionals, scientists, professional groups, and consumers, on the issues and concerns relating to the promotion of prescription drug products directly to consumers through print, broadcast, and other types of media. FDA is particularly interested in hearing the views of the groups most affected by direct-to-consumer promotion, including patients, caretakers, physicians, physicians' assistants, nurses, pharmacists, managed care organizations, and insurers.

DATES: The public hearing will be held on October 18, 1995, from 8:30 a.m. to 5:30 p.m., and October 19, 1995, from 8:30 to 12:30 p.m. Submit written notices of participation by September 15, 1995. Written comments will be accepted until December 29, 1995.

ADDRESSES: The public hearing will be held at the Quality Hotel—Silver Spring, 8727 Colesville Rd., Silver Spring, MD. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number 95N–0227. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has responsibility for regulating the labeling and advertising (promotional activities) for prescription drugs. Under section 201(m) of the act (21 U.S.C. 321(m), labeling is defined to include all "written, printed, or graphic" materials "accompanying" a regulated product. The Supreme Court has agreed with the agency that this definition is not limited to materials that physically accompany a product. The Court has deemed the textual relationship between the materials and the products to be fundamental (*Kordel* v. *United States*, 335 U.S. 345, 349–350 (1948)). In its regulations, FDA has given examples of things that it regards as labeling, including brochures, mailing pieces, calendars, price lists, letters, motion picture films, sound recordings, and literature (§ 202.1(l)(2) (21 CFR 202.1(l)(2)). Although the act does not define what constitutes a prescription drug "advertisement," FDA generally interprets the term to include information (other than labeling) that is sponsored by a manufacturer and is intended to supplement or explain a product. This includes, for example, "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (§ 202.1(l)(1)).

If an activity or material is considered to be either advertising or labeling, it must meet certain requirements. Labeling must contain adequate directions/information for use that is the "same in language and emphasis" as the product's approved or permitted labeling (21 U.S.C. 352(f)) and 21 CFR 201.100(d)). This requirement is generally fulfilled by including the full approved labeling for the product (the "package insert") with the promotional materials. The act specifies that, in addition to the identity of the product and its quantitative composition, advertisements must contain "other information in brief summary relating to side effects, contraindications, and effectiveness * * *"(21 U.S.C. 352(n)). FDA further defines this latter requirement in § 202.1(e). This requirement is generally fulfilled by including the sections of the approved labeling that discuss the product's adverse event profile, contraindications, warnings, and precautions. In addition, the act and regulations specify that drugs are deemed to be misbranded if their labeling or advertising is false or misleading in any particular or fails to reveal material facts (21 U.S.C. 352(a) and 321(n) and § 202.1(e)).

A. History of Direct-to-Consumer Promotion

The practice of promoting prescription drug products directly to consumers began to gain popularity in the early 1980's. Until that time, drug

manufacturers had typically limited their promotion to health care professionals. With the onset of direct-to-consumer promotion, the effectiveness of the regulatory scheme, was called into question.

To explore the ramifications of direct-to-consumer prescription drug promotion, FDA requested a voluntary moratorium on this practice in a September 2, 1983 policy statement. During the moratorium, FDA sponsored a series of public meetings and conducted research. In 1984, a symposium, jointly sponsored by the University of Illinois and Stanford Research Institute (SRI), was held to discuss consumer-directed prescription drug advertising from a broad research and policy perspective. In the Federal Register of September 9, 1985 (56 FR 36677), the moratorium was withdrawn in a notice, which stated that the current regulations governing prescription drug advertising provide "sufficient safeguards to protect consumers."

Since 1985, FDA has applied the act and the prescription drug advertising regulations to both professional and consumer-directed promotion on a case-by-case basis. There are no regulations that pertain specifically to consumer-directed promotional materials. FDA recognizes and accounts for the differences between health care professionals and consumers as recipients of drug promotion, such as differences in medical and pharmaceutical expertise, perception of pharmaceutical claims, and information processing. For this reason, FDA has monitored direct-to-consumer promotion to help ensure that adequate contextual and risk information, presented in understandable language, is included both to fulfill the requirement for fair balance and to help the consumer accurately assess promotional claims and presentations. Additionally, in a July 1993 letter to the pharmaceutical industry, as well as in numerous prior and subsequent public presentations given by FDA staff, the agency has requested that drug manufacturers voluntarily submit proposed direct-to-consumer promotional material prior to use, allowing FDA the opportunity to review and comment upon proposed materials before they reach consumers.

B. Current Issues in Direct-to-Consumer Promotion

1. General

The repercussions of direct-to-consumer promotion have been widely discussed. Proponents argue that direct-to-consumer promotion is of educational value and will improve the physician-patient relationship, increase patient compliance with drug therapy and physician visits, and lower drug prices. Opponents contend that consumers do not have the expertise to accurately evaluate and comprehend prescription drug advertising. Opponents also argue that such promotion is misleading by failing to adequately communicate risk information, and that such promotion will damage the physician-patient relationship, increase drug prices, increase liability actions, and lead to over-medication and drug abuse. Rigorous studies are needed to assess the actual effects of direct-to-consumer promotion and to help guide future policy.

In the last few years, FDA has received a number of citizen petitions that address direct-to-consumer promotion. The positions advocated by these petitions vary considerably. One petition requests that FDA ban direct-to-consumer advertising of prescription drugs. A second petition requests that FDA not adopt or institute any significant new restrictions to existing regulations nor mandate prior approval of consumer-directed advertising. A third petition, recently updated and reissued by the petitioner, contends that consumer-directed prescription drug advertising should not be regulated under § 202.1, and it also contends that FDA should promulgate new regulations to address prescription drug advertisements directed to consumers. The petitioner further contends that, until such time as new regulations are established, FDA should issue a policy statement that prescription drug advertisements directed to the general public are exempt from the advertising regulations. Another petition, recently received by FDA, reiterates these concerns and also raises First Amendment issues. The range of actions requested in these petitions is indicative of the diversity of views regarding direct-to-consumer promotion. FDA recognizes the importance of the issues raised by these petitions, and FDA intends that one of the purposes of the public hearing will be to assist the agency in responding to these petitions.

2. Types of Direct-to-Consumer Promotion

There are three broad categories of direct-to-consumer promotion of prescription drugs: (1) "Product-claim," containing safety and efficacy claims about a particular drug(s); (2) "help-seeking," containing information about a disease or condition and a recommendation for the consumer to consult a health care provider, when appropriate, while excluding discussions of specific treatments or drugs; and (3) "reminder," containing the name of the drug and other limited information, but excluding all representations or suggestions about the drug(s).

3. Product-Claim

Product-claim promotional materials contain safety and efficacy claims about a specific prescription drug product. The regulations require that these materials present a balanced view of the drug (§ 202.1(e)(5)(ii)). Claims of drug benefits, such as safety and efficacy, must be balanced with relevant disclosures of risks and limitations of efficacy. This balanced presentation of drug therapy is commonly referred to as "fair balance."

Currently, most consumer-directed product-claim materials are limited to one drug product and do not compare drugs, or classes of drugs, with each other. Proponents of this noncomparative format argue that consumers do not have the contextual knowledge required to critically evaluate comparative claims. Opponents contend that consumers could evaluate comparative claims that are properly framed and fairly balanced.

4. Help-Seeking

Help-seeking promotional materials encourage consumers with particular symptoms, conditions, or diseases to consult their doctor to discuss general treatment options, but do not mention specific prescription drug products.

If the only available treatment for a condition is a specific prescription drug product, help-seeking materials may not be employed. In such a case, materials focusing on the condition would, by implication, promote the product. In addition, help-seeking materials may not include "linkages," i.e., logos, tag lines, graphics, etc., to product-specific materials. Linkages create a clear association between a disease and a prescription drug, resulting in the interpretation of the help-seeking material as product-claim material. Help-seeking materials that include linkages are regulated as product-claim materials.

As direct-to-consumer promotion has become more sophisticated, some opponents have questioned FDA's decision not to regulate help-seeking materials. They argue that even in the absence of direct linkages, many consumers are able to connect the sponsoring manufacturer with a specific prescription drug.

TAB 19

New or Rebuilt

[¶ 7765] Nature of Components or Previous Use

It is unfair to misrepresent products which are used or second-hand or rebuilt or made from used materials as new (.40), or misrepresent the degree of use by such phrases as "slightly used" (.90). Subject to varying circumstances, a tentative outer limit of six months has been established for designating a product as "new" (.20).

It has been recognized that the consuming public has a preference for new or unused products (.87). Thus, the prior use of merchandise that has been tried and returned by prospective purchasers must be disclosed, even though it has been "refurbished" or returned to a good-as-new condition, the FTC has stated.

Affirmative disclosure of the fact that products are used or second-hand is required. For such rulings, see ¶ 7557. As to "seconds" and "rejects," see ¶ 7553.

The term "rebuilt" should not be used unless the article is rebuilt (.60). Representations that articles were rebuilt by the original manufacturer are unfair if untrue (.70).

Annotations to ¶ 7765 Appear Topically Below, as Follows:

New

.20 "New" after period of time.—The time period during which a particular product may be called "new" will depend upon circumstances and is not subject to precise limitations. Considering the absence of precedent, the Commission thought it preferable to establish a tentative outer limit for use of the claim "new," namely, six months. The general rule would apply, unless exceptional circumstances warranting a period of time either shorter or longer than six months were shown to exist.

Advisory Opinion No. 120.

.201 After reconsidering its tentative six month limit on the permissible period of time during which a product may be called "new," the Commission stated that the rule had not been in effect long enough to determine whether a change would be required but added that a marketing program which lasts for more than six months and covers less than 15% of the population would not disqualify an eventually widely marketed product from being called "new."

Advisory Opinion No. 146.

.202 It was deceptive to market as "new" ten-year-old equipment even though the equipment had never been used and was still in the original shipping cartons. The company was not the original manufacturer and had recently been licensed to manufacture similar equipment.

Advisory Opinion No. 325.

.203 An examiner's ruling that hearing aids could be advertised as "new" for a period of one year after introduction to the hearing aid market was approved. Although the one year period was based on a liberal construction of FTC Advisory Opinion No. 120, it appeared to be justified in view of the infrequent developments of the technology and advancements in the use of transistors and miniaturization of electronic components in the hearing aid industry.

Dkt. 8791.

.30 New and up-to-date reference books.—Representations that an encyclopedia was a "recently completed, new, and up-to-date encyclopedia" were prohibited.

Standard Education Society v. FTC (U.S. Sup. Ct. 1937) 1932-1939 TRADE CASES ¶ 55,170, 302 U.S. 112 (FTC Dkt. 1574).

Similarly:

Consolidated Book Publishers v. FTC (CCA-7; 1931) 53 F. 2d 942 (FTC Dkt. 1538).

.301 Reference books should not have been described as new when they were composed in substantial part of material reprinted from another, or as up-to-date when based on statistics over 15 years old and when terminal dates for histories go back approximately ten years. The FTC said in its opinion:

"That use of the terms 'new' or 'completely new' to designate a reference publication composed in substantial part of material reprinted from another being contemporaneously marketed

under another title has the capacity and tendency to deceive is therefore obvious, and requires no further comment. On the other hand, the order contained in the initial decision appropriately recognizes the respondents' right to make truthful and nondeceptive statements in the future respecting newness in the manner of presenting constituent information. * * *

"* * * Whereas the book has a 1957 copyright and introductory material identifies it as complete in scope and up-to-date in statistics and population figures, it appears from their testimony that the census data used in many instances were those for the year 1940. Also, the terminal dates for certain of the political and economic histories on foreign countries go back to the late 1940's and early 1950's."

Dkt. 7245.

.302 Similar misrepresentation prohibited:

Books—as new and up-to-date.

Dkts. 2433, 2761, 7244; Stip. 2387.

Dictionaries—as new, rewritten, or revised.

Dkts. 4440, 4634.

Encyclopedia—as "one of the world's great encyclopedias," containing authoritative, complete and up-to-date information on all subjects, manufactured on superior quality paper.

Dkt. 5513.

Encyclopedias—claim that encyclopedia was entirely new and not yet on the market.

Dkt. 5580 (affirmed in *Standard Distributors, Inc. v. FTC* (CA-2; 1954) 1954 TRADE CASES ¶ 67,689, 211 F. 2d 7; rehearing denied (CA-2; 1954) 1954 TRADE CASES ¶ 67,712, 211 F. 2d 7; order modified by the Commission in 1955.)

Encyclopedias—misrepresentation as to revision date.

Dkts. 2351 (dismissed), 2511, 2652, 2893, 3349, 3503; Stips. 1937, 3242.

Garden encyclopedia—as "revised" when in fact book had not undergone any material revision and was the same or substantially the same volume previously sold by respondent; as containing a "new supplement" when in fact supplement was substantially same supplement previously included; as containing information as to "latest developments and methods" when in fact book did not contain such information (it had been charged that encyclopedia had undergone no general revision since its original publication 26 years before).

Dkt. C-694.

"New Modern Encyclopedia"—as most up-to-date encyclopedia in existence and as containing complete history of any event or episode of World War II.

Stip. 8268.

.35 New inventions or processes.—Representations that a "waterproofing" paint to be applied to masonry "works on entirely new principle" were prohibited. The advertising was open to the construction that the combination of materials in the "waterproofing" paint constituted, at least to some extent, the supposed "new principle," and the fact was otherwise.

Prima Products, Inc. v. FTC (CA-2; 1954) 1954 TRADE CASES ¶ 67,663, 209 F. 2d 405 (FTC Dkt. 5622).

.351 Misrepresentations that products were new inventions or innovations, prohibited:

Address books—as new and original.

Stip. 8412.

Canning device—as involving newly discovered principle.

Stip. 3306.

Carbon paper—as new, novel and efficient manufacturing process with resultant enhancement of quality and serviceability.

Stip. 2219.

Carpeting—special manufacturing process available for first time.

Dkt. 8846.

Cigarettes with filter tip—new and revolutionary and only cigarettes on market so designed.

Stip. 3144.

Electroplating—claims that brush method of electroplating was new and that the device would work as well on rough as on smooth surfaces, producing equal results as those obtained through use of immersion method of electroplating.

Dkt. 5582.

Furnace converter—"amazing new wartime invention."

Stip. 3857.

Hair curling preparations—new discovery.

Dkt. 7280.

Hair dryers—new concept or discovery.

Dkt. C-227.

Hearing aid—bone conduction type as a new invention which was invisible and would provide normal hearing.

Dkt. 6414.

Insecticide—that ingredients were entirely new.

Stip. 8131.

Intercommunicative system called "Flash-A-Call"—new invention or innovation.

Dkt. 5540; Stip. 3591.

Medicinal preparation for arthritis—as new or magic formula.

Stip. 9366.

Paint—"Cello-Nu" as new paint discovery.

Stip. 8053.

Paint remover—new and unique formulation.

Stip. 8191.

Photographs—"new" or "different."

Stip. 3326.

Plastic building material—entirely different from any other product.

Stip. 7804.

Plastic metal —as new and different product.

Stip. 7958.

Printing by thermographic process—representing that this was a new process when it had been used in the trade for years.

Dkt. 5762; Stip. 8653.

Sedatives—new medical or scientific discovery.

Dkts. 8399, 8400.

Solders—contained a metal or an additive which is new, special or unique.

Dkt. C-141.

.40 New, meaning unused.—Representations that hats made in whole or in part from old, used, or second-hand materials were new, or were composed of new materials, were prohibited.

Schachnow v. FTC (CCA-3; 1941) 1940-1943 TRADE CASES ¶ 56,118 (FTC Dkt. 2047).

.401 Misrepresentation of products as new, prohibited:

Aluminum castings—advertised as "only new ingot metals" when they were manufactured both from virgin ingots and from misrun or scraped castings.

Dkt. 2954.

Automobiles—auto vendors representing themselves falsely as manufacturers and vendors of new motor trucks and automobiles for export sale, advertising such machines as having standard factory equipment, when in fact the respondents made a practice of shipping motor trucks which were not new, consisting of old, used, rusted, or second-hand parts without complete factory equipment, and gave buyers no opportunity for inspection prior to shipment, and refused to refund payments in excess of agreed prices or for trucks returned or rejected for reason.

Dkts. 904 (dismissed), 1276, C-1647.

Automobiles—a dealer was prohibited from representing as "new," automobiles left over from the previous model year.

Dkt. C-1347.

Automobiles—manufacturers were not entitled, as a matter of law, to sell as "new" vehicles used for Environmental Protection Agency mileage tests. Each manufacturer's testing might raise unique questions. Thus, in response to an advisory opinion request from the EPA, FTC deferred a definitive opinion until it received a request from a manufacturer.

Advisory Opinion (*U.S. Environmental Protection Agency*, March 7, 1975).

Automobiles—dealers were prohibited from representing that any vehicle is new when it has been used in any manner other than the limited use necessary in moving or road testing prior to delivery to the customer. Previous use of such vehicles had to be disclosed in advertising and oral solicitations and on window stickers, and that the window stickers also contain the following instruction: "FOR EXACT MILEAGE, SEE ODOMETER."

Dkts. C-2550, C-2551.

Similarly: Dkts. 8974, 8975.

Ball bearings.

Stip. 2168.

Bedding—that bedding composed in whole or part of "sweeps" was composed of new material.

Dkt. 5024; Stips. 3449, 7538.

Bristles.

Stip. 3965.

Check writing machines.

Dkt. 602; Stips. 1999, 8481.

Dresses.

Dkt. 6605 (dismissed).

Electric shavers—reconditioning shavers returned after free home trial and selling them as new and unused.

Dkt. 6543.

Electrical apparatus.

Stip. 2644.

Electrical appliance.

Dkt. 5645.

Encyclopedias.

Dkt. C-2152.

Feathers.

Dkt. 6161 (petition to review dismissed in *Salisbury Co. v. FTC* (CA-8; 1956) 1956 TRADE CASES ¶ 68,364, 230 F. 2d 954); Stip. 3646.

Files.

Dkt. 4020; Stips. 508, 2017, 2179, 2402, 3971, 4102, 8994.

Fruit jars.

Dkt. 4192.

Furniture.

Stip. 3581.

Furs.

Dkts. 2787, 3456; Stips. 2843, 3261, 3402.

Golf balls—previously used, rewashed or repainted, according to the FTC.

Dkt. C-1038.

Hats.

Dkts. 1895-1899, 1900 (dismissed), 1901-1904, 2044, 2045, 2046, 2047 (modified and affirmed in *Schachnow v. FTC* (CCA-3; 1941) 1940-1943 TRADE CASES ¶ 56,118), 2048 (order to cease and desist set aside and complaint consolidated with complaint No. 3838), 2049, 2050 (dismissed), 2061, 2075, 2499, 2647, 2651, 2923, 3020, 3230, 3473, 3493, 3830, 3837, 3838, 4245, 4628, 4629, 4633, 4679, 4742 (closed), 5134 (closed), 5246, 5331, 5461, 5535, 5694, C-990;

Stips. 1767, 1791, 1798, 1807, 1808, 1809, 1818, 2050, 2081, 2084, 2143, 2152, 2153, 2274, 2873, 2879, 3001, 3179, 3347, 3533, 3592, 3721, 3838, 3839, 3855, 3942, 3979, 4160, 4161, 4162, 4173, 7564, 7603, 7771, 7973.

Ice creepers.

Stip. 8499.

Iron specialities.

Dkt. 820.

Jewelry.

Dkt. 7011.

Lawn mowers—which were used or made of used parts.

Dkt. 6667.

Mattresses and bedding.

Dkts. 1970, 1977, 3199, 3324, 3809, 4072, 4073, 4483, 4780, 5874; Stips. 117, 146, 193, 342, 3006, 3007, 3009, 3010, 3011, 3012, 3059, 3068, 3449, 3467, 7858.

Oil—reclaimed oil as new and unused and made from virgin crude oil.

Dkts. 4370, 4524, 6339, 6492, 6669, 6709, 6717; Stips. 2920, 3301, 3584, 8784, 8785, 8786, 8831, 8834, 8835, 8841, 8852, 9124, 9218, 9286, 9290, 9471.

Oil burners.

Stip. 1247.

Orthoptic machines.

Dkt. 3813.

Paint—reconditioned, redissolved paint as fresh stock.

Dkts. 4014, 4088.

Pianos.

Dkts. 541 (dismissed), 6551.

Plumbing supplies.

Dkt. 1848 (application for enforcement dismissed *FTC v. Crancer and Fleischman doing business as Alleghany Tube and Steel Co.* (CCA-8; 1935) 76 F. 2d 1008); Stip. 7743.

Radio and television tubes.

Dkts. 7019, 7097.

Sewing machines.

Dkts. 6685, 7697.

Shoes.

Dkt. 4780.

Silverware.

Dkt. 3028.

Spark plugs.

Dkts. 2144, 2291, 3392 (petition for review dismissed *Sanders doing business as Perfect Reconditioned Spark Plug Co. v. FTC* (CCA-2; 1941), 3534, C-1730; Stips. 3278, 4056.

Telephone instruments.

Dkt. 921.

Television picture tubes—containing used parts.

Dkts. 8105, C-154.

Television sets.

Dkt. 6411.

Theatre equipment.

Stip. 2651.

Tires—"factory fresh" or stock of particular year; that "take-off" or "change-over" tires (which had been removed from new cars prior to sale or delivery and had had some use) were new.

Dkt. 6626.

Tires—repairing old tires, coating said tires with rubber or a composition, remarking them, and advertising them for sale in such a manner as to lead public to believe tires new.

Dkts. 243, 252 (dismissed), 253, 403, 494 (dismissed), 874, 2333, 5581, 7004; Stip. 1405.

Truck replacement parts—"new," misleading purchasers into belief that parts were of recent manufacture and designed for use on current model trucks; when such parts were in fact new in sense that they had not been used, and word "new" was used to described them "new" should be conspicuously accompanied by other words indicating clearly on what particular model of truck parts were designed for use.

Stip. 1279.

Typewriters.

Dkts. 34, 35, 36, 37.

Umbrellas.

Stips. 3835, 3837, 4024, 4028, 4029, 4032, 4036-4039, 4048-4050, 4068, 4095, 4100, 4165.

Voltage regulators.

Stip. 8756.

Watches.

Dkt. 4595 (closed); Stips. 1163, 1777, 2155, 3506, 3509, 4112.

Watches and jewelry—which had been rebuilt.

Dkt. 7011.

Wearing apparel.

Dkts. 2561, 3442, 3576, 4016, 4665, 4780, 5023, 5034 (closed), 5170, 5461, 6496; Stips. 2045, 3594, 3693, 3843, 3942, 4015, 7552.

.45 New style.—Representing that old style hats were of latest styles or that salesmen's samples were new hats, discontinued.

Stip. 7524.

.50 "New" to marketing area.—In advertising "newness" the implication is that the product is new, i.e., "recently invented, discovered or developed," not that it is new to the marketing area. Therefore, an examiner's order providing that if a product is new in a marketing area but not known in another a company may advertise the product as "new" in the area in which it is not yet known for a period of one year was incorrect.

Dkt. 8791.

.60 Rebuilt.—Representing articles as rebuilt when they had been repaired but not rebuilt, prohibited:

Adding machines.

Dkt. 725.

Transmissions—using the term "factory rebuilt" except to describe a transmission rebuilt in a factory engaged in such rebuilding.

Dkt. 8713.

Vacuum cleaners—designating as "rebuilt" any vacuum cleaner which had not been actually disassembled, reconstructed and refinished; and representing that all new parts were installed where needed when in fact such parts are used, and that an advertised machine came equipped with new or complete attachments when in fact such attachments were old, misfit, unusable or missing.

Stip. 3859.

Vacuum cleaners — misrepresentations concerning newness or make of the parts used in rebuilding vacuum cleaners.

Stip. 3495.

Watches—as "rebuilt" when they had not been overhauled, reconditioned or reconstructed.

Stip. 633.

.601 Reclaimed fuses broken down to their smallest components and inspected to meet new parts standards must be labeled as "rebuilt" or "remanufactured." It would be deceptive without a disclosure to sell merchandise resembling and having the appearance of a new product but actually composed of reclaimed materials, since the public has a preference for merchandise composed of new materials. If adequate disclosure is made on advertising materials and on the cartons, disclosure of the nature of the product would not be necessary on technical instructions.

Advisory Opinion No. 84.

.70 Rebuilt by original manufacturer.—Misrepresenting rebuilt articles as rebuilt by or at the factory of the original manufacturer:

Sewing machines—representing that the rebuilt sewing machines were rebuilt by or at the factory of the original manufacturer when in fact they were rebuilt by respondent sewing machine company.

Dkt. 5817.

.80 Reconditioned in factory.—"Reconditioned in factory" prohibited to describe tires which had not been reconditioned in a factory or manufacturing plant.

Dkt. 6626.

.82 "Renovated".—A complaint charged that by using the word "renovated", and by not clearly disclosing the true nature of hat bodies, respondents failed to disclose adequately that their hats were made from previously used and worn hat bodies as distinguished from hats made entirely from new and unused materials which had not previously been sold to consumers.

Dkt. C-1034.

.821 Hats could not be represented as "John B. Stetson Renovated Hats" when it was alleged that they were made from used and worn hats and that not all of them were originally manufactured by Stetson.

Dkt. C-1015.

.87 "Returned" and "refurbished."—The FTC issued a policy statement concerning merchandise that has been used by purchasers on a trial basis, returned to the seller, "refurbished" and then resold as new. Usually no disclosure of previous use is made to the ultimate purchaser. The FTC stated that the consuming public has a preference for new or unused products compared to those that have been previously used. Qualitative equivalence does not change the fact that substitution of a used product for a new one without disclosing such fact is unlawful. Clear and conspicuous disclosure of prior use must be made in all the marketer's advertising, sales promotional literature and invoices concerning the product, on the container in which the products are packed and, if the product has been refurbished or otherwise has the appearance of being new, on the product with sufficient permanency. The FTC suggested that the marketers of products maintain adequate inventory control records to enable them to demonstrate that returned merchandise was not replaced in inventory and resold without disclosing the fact of its previous use. The Commission made it clear that this policy concerning returned merchandise applies only to merchandise that has been used, and not to merchandise that has merely been inspected but not used. *FTC Statement of Enforcement Policy*, January 4, 1969.

A manufacturer was prohibited from misrepresenting used photographic equipment as new and failing to disclose its true nature clearly and conspicuously. The complaint alleged that used and unused photographic equipment returned for replacement or credit were intermingled in such a manner that one category could not be distinguished from the other, and that the firm refurbished and repackaged some of this returned equipment and then marketed it as new without any disclosure that it had been or may have been used.

Dkt. C-2433.

Similarly: Dkt. C-2291.

.90 Slightly used.—Use of the words "slightly used" or "slightly" and other words of like meaning which tend to convey the belief that previous use or wear of such second-hand clothing was slight, when in fact the extent, degree or nature of such use or wear would be improperly designated or referred to as "slightly" or "slight," discontinued.

Stip. 3594.

"Slightly used" to describe tires on which approximately one-half the tread had been worn away.

Stip. 7927.

Tires as less than one year old and free from boots and patches, discontinued.

Dkt. 3973.

TAB 20

(2) The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise sole jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics;

(3) The initiation of proceedings involving the same parties by both agencies simultaneously shall be restricted to those highly unusual situations where it is clear that the public interest requires two separate proceedings. For the purpose of avoiding duplication of work and to promote uniformity and consistency of action in areas where both agencies have a concern and the actions of one agency may affect proceedings by the other, it is recognized that such liaison activity is required,

In instances where:

(a) The same or similar claims are found in both labeling and advertising;

(b) written, printed or graphic material may be construed as either advertising or as accompanying labeling or both, depending upon the circumstances of distribution;

(c) the article is a drug or device and appears to be misbranded solely because of inadequacy of directions for use appearing in the labeling for conditions for which the article is offered in advertising generally disseminated to the public.

Updated FTC-FDA Liaison Agreement—Advertising of Over-the-Counter Drugs

[¶ 9851]

(Issued September 9, 1971; approved by the Commissioner of Food and Drugs, April 27, 1971 and the Chairman of the Federal Trade Commission, May 14, 1971.)

I. Purpose:

a. It is agreed that the common objective of preventing injury and deception of the consumer requires that the statutory authorities and procedures, and the manpower and other resources available to each agency are so employed as to afford maximum protection to the consumer. This means joint planning of coordinated programs, exchange of information and evidence to the extent permitted by law, by the staffs of both agencies in appropriate undertakings and the careful selection of the procedure of either agency (or simultaneously by both) promising greatest benefit to the public.

b. In order to provide for exchange of complete information so that both agencies will be utilized to the maximum effectiveness in the public interest, each agency will designate a liaison officer to serve as the primary source of contact. These liaison officers will be responsible for currently informing each other of proposed proceedings and of internal developments in areas of joint concern to the extent that such information is not privileged.

II. Designated liaison officers.

a. *Federal Trade Commission.* The Assistant to the General Counsel of the Federal Trade Commission.

b. *Food and Drug Administration.* The Associate Commissioner for Compliance of the Food and Drug Administration.

III. In order to facilitate the purposes of this agreement, it is specifically agreed that:

a. With the exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics. In the absence of express agreement between the two agencies to the contrary, the Commission will exercise primary jurisdiction over all matters regulating the truth or falsity of advertising of foods, drugs (with the exception of prescription drugs), devices, and cosmetics;

b. The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising. In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise primary jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics;

c. The initiation of proceedings involving the same parties by both agencies shall be restricted to those highly unusual situations where it is clear that the public interest requires two separate proceedings. For the purpose of avoiding duplication of work and to promote uniformity and consistency of action in areas where both agencies have a concern and the actions of one agency may affect proceedings by the other, it is recognized that such liaison activity is required in instances where:

(1) The same, or similar claims are found in both labeling and advertising;

(2) Written, printed or graphic material may be construed as either advertising or as accompanying labeling or both, depending upon the circumstances of distribution;

(3) The article is a drug or device and appears to be misbranded solely because of inadequacy of directions for use appearing in the labeling for conditions for which the article is offered in advertising generally disseminated to the public.

IV. It is further agreed that:

a. Regulations promulgated under section 5 of the Fair Packaging and Labeling Act by the respective agencies for the commodities for which they have jurisdiction under that Act, shall be as uniform as possible.

V. Meetings to be held:

a. The respective liaison officers will hold meetings from time to time to discuss matters of concern to each agency and that they will be accompanied by whatever staff they may deem appropriate and necessary.

VI. Period of agreement:

This agreement, when accepted by both parties, covers an indefinite period of time and may be modified by mutual consent of both parties or terminated by either party upon thirty (30) days' advance written notice. (36 *Federal Register* 18539, September 16, 1971.)

TAB 21

U S Food and Drug Administration
Center for Drug Evaluation and Research

Division of Drug Marketing, Advertising and Communications

Frequently Asked Questions (FAQs)

Click on a topic to link to questions and answers.

Consumer-Directed Advertisements

What are the general requirements for prescription drug advertisements directed toward consumers?

The same statute and regulations apply regardless of the audience targeted by a prescription drug advertisement. The Federal Food, Drug, and Cosmetic Act (the act) requires that all drug advertisements contain (among other things) information in brief summary relating to side effects, contraindications, and effectiveness. Because of this statutory wording, this requirement

has become known as the Brief summary. The current advertising regulations specify that this information disclosure needs to include **all** the risk information in a product's approved labeling. Typically, print advertisements will include a reprinting of the risk-related sections of the product's approved labeling (also called full prescribing information or the package insert). Sponsors, however, can write this risk information in language appropriate for the targeted audience; FDA encourages this approach.

In addition to the specific disclosure requirements, advertisements cannot be false or misleading or omit material facts. They also must present a fair balance between effectiveness and risk information. FDA has consistently required that appropriate communication of effectiveness information includes any significant limitations to product use.

How do prescription drug broadcast advertisements differ from print advertisements?

Current regulations specify two requirements that all prescription drug broadcast advertisements must meet. First, broadcast advertisements must include the product's most important risk-related information in the audio or audio and visual parts of the advertisement. This is sometimes called the major statement. This requirement is not addressed by the guidance. Second, broadcast advertisements must contain either a brief summary of the advertised product's risk information, or alternatively, make adequate provision for disseminating the product's approved labeling in connection with the ad. Thus, the regulations for broadcast advertisements recognize broadcast's inherent limitations by providing an alternative mechanism for meeting the act's information disclosure requirement.

What needs to be included as part of the major statement requirement?

The major statement must include all of the most important risk information related to the product. Because risks vary from product to product, the amount of information disclosed for any particular product to meet this requirement will vary as well.

How does a product's brief summary differ from its approved labeling?

The brief summary is generally shorter -- sometimes significantly so. The brief summary typically includes only the risk-related sections of the product's labeling. This is because the advertising text itself generally meets the requirement for including effectiveness information by giving the product's indication (i.e., what it is used for), and any limitations concerning how and when the product should be used. In contrast, product labeling includes non-risk-related information, including all effectiveness information (sometimes even about the clinical studies used as the basis for product approval), how it should be taken (dosage information), how the drug product is supplied (e.g., the quantity of drug in each pill), and information about how the product works in people's bodies.

Does FDA intend to do anything about the brief summary information? I've heard a lot of concerns about its value for consumers.

FDA has also heard concerns about the lack of value of the required information from some individuals and groups. It has heard from others that consumers should get full disclosure of risk information. The agency intends to address these concerns fully through the rulemaking process. In the interim, the agency encourages product sponsors to provide consumers with nonpromotional, consumer-friendly information consistent with product labeling, along with

the information required by the act and the regulations. As mentioned above, in the case of print advertisements, FDA encourages sponsors to write their product brief summaries in consumer-friendly language.

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Drug of Choice

May the phrase "drug of choice" be used in advertising or labeling?

The phrase "drug of choice," or any similar phrase or presentation, used in an advertisement or labeling would make a superiority claim and, therefore, the advertisement or labeling would require substantial evidence to support that claim.

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Drug Name Size

Does the full prescribing information or the brief summary type have to be any particular size?

No, but the regulations specify size in sections 201.10(g)(2) and 202.1(b)(2) which state: "The established name shall be in printed letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast and other printing features."

Does "half as large" refer to point size or actual type size?

DDMAC has interpreted "half as large" to be actual size, not point size, of upper and lower case letters in the proprietary and established drug names.

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"FDA-Approved"

May an advertisement or labeling piece include the phrase "FDA approved"?

Yes, if the manufacturer or sponsor has received a letter stating that the product has been approved. Effective on the date of implementation, the Food and Drug Administration Modernization Act of 1997 eliminated Section 301(l) of the Federal Food, Drug, and Cosmetic Act that prohibited "The using . . . of any representation or suggestion that approval of an application with respect to such drug or device is in effect . . . ."

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"New"

How long may the word "new" be used in promotional labeling and advertisements for a newly approved product, indication, or dosage form?

DDMAC generally considers that "New" is an accurate description of the marketing phase for six months from the time a product is initially marketed. This should be distinguished from the time the product is cleared by FDA for marketing.

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Package Inserts

Does it matter where a package insert is placed on a labeling piece, such as on a calendar or a brochure with a pouch?

The package insert can be anywhere as long as the labeling piece states clearly where the package insert is located and as long as the package insert accompanies the piece.

Are package inserts required in all labeling pieces for products that are the same except for different strengths or dosages?

Yes. Even though products may be very similar, package inserts may be different for different dosage forms or different delivery systems for the same drug. The regulations would require a package insert for each dosage form and delivery system for which claims appear in the promotional labeling piece. Some drug products, however, have multi-dosage form package inserts. In those cases, the same package insert could be attached to each piece, even if the dosage forms or delivery systems were different.

Does a package insert in another language also have to be submitted in English?

Yes. Package inserts have to be submitted in English and not only in the foreign language.

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Postmarketing Reporting

Where do the regulations state the requirement for submitting prescription drug advertisements and labeling?

Under 21 C.F.R. 314.81(b)(3)(i):

Section 314.81 Postmarketing reports.

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(b) *Reporting requirements*. The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

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(3) *Other reporting--(i) Advertisements and promotional labeling*. The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product . . . .

(See Selected Provisions of the Act and Regulations for the entire paragraph.)

When do promotional materials need to be submitted to DDMAC?

Pursuant to 314.81(b)(3)(i), submissions must be made " . . . at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product."

Do all promotional materials for prescription drugs have to be submitted to DDMAC?

The regulations for submitting materials apply to holders of NDAs, ANDAs, and antibiotic applications. Manufacturers of pre-1938 products and products that have declared "not new drugs" are not required to submit specimens. All products have labels and prescribing information, however, and products without approved labeling have permitted labeling. Permitted labeling indicates FDA agrees with the label or labeling and permits its use. A manufacturer of a product with permitted labeling is responsible for assuring that advertisements and promotional labeling pieces are consistent with the product labeling.

What form should applicants use to submit materials to FDA?

Form FDA 2253 Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use.

How can I obtain an Form FDA 2253?

Address

To whom should I send the materials?

Two copies of all materials should be sent to:

Division of Drug Marketing, Advertising, and Communications
5600 Fishers Lane, HFD-40
Rockville, MD 20857

Upon arrival, the material will be logged in for tracking and assigned to a reviewer in DDMAC.

Who is responsible for submitting a Form FDA 2253 if the manufacturer and distributor are different companies?

Either company may submit the specimens, however, the applicant is ultimately responsible for compliance with 21 CFR 314.81(b)(3).

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Presentation of Information

Can the layout or the way information is presented affect whether an advertisement or labeling piece is in compliance with the regulations?

Yes, 21 CFR 202.1(e)(7)(viii) states that an advertisement may be false, lacking in fair balance, or otherwise misleading if it:

"Fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis."

For example, the presentation below of the word benefits and the word disadvantages would not be considered comparable. Although the words are the same point size, the color and contrast with the background make the word benefits much more noticeable than the word disadvantages.

BENEFITS disadvantages

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Pre-distribution Submissions

Does FDA approve advertisements and promotional labeling before use by the company?

No, except for accelerated approval products and, in rare instances, when FDA may require pre-approval of promotional materials as part of an enforcement action. However, DDMAC provides opinions on proposed advertisements and labeling pieces before use upon request by an applicant.

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Reminder Advertisements and Labeling

What is a reminder advertisement?

Under 202.1(e)(2)(i), reminder advertisements are identified as an exemption to the advertisement regulations, including the provisions under 202.1(e) to provide a brief summary. Reminder advertisements " . . . call attention to the name of the drug product but do not include indications or dosage recommendations for use of the drug product. . . . and, optionally, information . . . containing no representation or suggestion relating to the advertised drug product." Reminder advertisements cannot make a representation about the product or suggest a use for the product.

What is reminder labeling?

Under 201.100(f), reminder labeling is " . . . labeling which calls attention to the name of the drug product but does not include indications or dosage recommendations for use. . . . and, optionally, information . . . containing no representation or suggestion relating to the drug product." Reminder labeling is exempted from the provisions under 201.100(d) to provide the full prescribing information.

Can a reminder advertisement compare one product to another or say one product is an alternative for another?

No. Such a comparison would imply the indication, and then the advertisement would no longer meet the exemption criteria.

Does FDA limit the amount of money that can be spent on reminder advertisements or reminder labeling pieces or regulate the types of objects (such as pens, cups, calendars, etc.) that can be used as reminder advertisements or reminder labeling pieces?

FDA regulations do not limit how much money companies may spend on reminder advertisements and labeling pieces, nor do the regulations limit the types of objects that can be used. The regulations, however, limit the type of information that can be presented in reminder advertisements and labeling pieces, and not just the written information, but information that may be portrayed though graphics, design, or some other visual representation.

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Miscellaneous Questions

Are the advertising and labeling procedures for orphan drugs and regular NDA products the same?

Yes.

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